NCI CANCER FAMILY REGISTRIES

ASSURANCE FORM FOR BIOSPECIMENS

To ensure compliance with the Office of Human Subjects Research (OHSR), Department of Health and Human Services (DHHS) regulations for the protection of human subjects (45 CFR Part 46), before biospecimens can be shipped from the NCI Cancer Family Registries, the principal investigator and the legally binding, authorized institutional official must sign this statement agreeing to adhere to the following conditions. The signed assurance form should be returned to the site providing the biospecimens.

USE AND WARRANTY

The recipient acknowledges that the conditions for use of biospecimens are governed by the Institutional Review Board (IRB) of the recipient's institution in accordance with DHHS regulations (45 CFR Part 46). The recipient agrees to comply fully with all such conditions and to report promptly to the NCI Cancer Family Registries any proposed changes in the research project and any unanticipated problems involving risks to subjects or others. The recipient remains subject to applicable state and local laws or regulations and institutional policies that provide additional protections for human subjects. The recipient agrees not to try to identify or contact the donor subject from whom the biospecimen was derived. Biospecimens are provided as a service to the research community. They are provided without warranty of merchantability or fitness for a particular purpose and without any other warranty, expressed or implied. All materials remaining after the approved research is completed must be destroyed unless approval for use in another CFR project has been obtained. If the principal investigator desires to use any remaining materials after the project specifically approved by the relevant CFR Steering Committee is completed, a separate application for such use of the resources must be submitted to the relevant CFR for approval by that CFR Advisory Committee or Steering Committee for approval before proceeding with such study.

For State Institutions: The recipient institution agrees to be responsible for any claims, costs, damages, or expenses resulting from any injury (including death), damage, or loss that may arise solely from the use of the biospecimen to the extent permitted under the laws of this state. This provision shall also apply to any byproducts or derivative of the biospecimens.

For U.S. Government Laboratories: The United States assumes the liability for any claims, damages, injury, or expenses arising from the use of material or any byproduct or derivative, but only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171).

For All Other Institutions: The recipient institution agrees to indemnify and hold harmless the United States Government, the site providing the biospecimens, and the contributor from any claims, costs, damages, or expenses resulting from any injury (including death), damage, or loss that may arise from the use of the biospecimen. This provision shall also apply to any byproducts or derivatives of the biospecimen.

HUMAN EXPERIMENTATION

Human experimentation utilizing the research materials may not be undertaken without additional prior review and approval by an IRB at the recipient site, which must be convened under an applicable OHSR-approved Assurance.

PROHIBITIONS ON RESALE AND REDISTRIBUTION INCLUDING RESTRICTIONS ON COMMERCIAL USE

The purpose of the NCI Cancer Family Registries is to stimulate and facilitate research in breast or colon cancer, leading to a better understanding of the underlying genetic and cellular processes, to the identification and function of disease-related genes, and to the diagnosis and treatment of this disease. There is no restriction on development of commercial products resulting from the knowledge gained from studies using CFR biospecimens. However, use of the biospecimens and products derived from them are subject to the prohibitions and restrictions below, to which the undersigned agree.

The undersigned agree that:

Products derived from the biospecimens obtained from the NCI Cancer Family

Registries may not be sold or distributed with or without charge to a third party. Expansion or subdivision of cell cultures or replication or subdivision of DNA or other biospecimens, or use of products derived from the biospecimens obtained from the NCI Cancer Family Registries for distribution to laboratories other than the original recipient, with or without charge, is prohibited.

BIOHAZARD

All cultured human cells have the potential for carrying viruses, latent viral genomes, and other infectious agents in an inapparent state. The cell cultures shipped by the Cancer Family Registries should, therefore, not be treated as if they are free of contamination. These cells should always be handled carefully by trained persons under laboratory conditions that afford adequate biohazard containment following MINIMUM SAFETY GUIDELINES RECOMMENDED FOR WORKING WITH HUMAN CELL CULTURES. By accepting these cells, the undersigned assume full responsibility for their safe and appropriate handling.

We, the undersigned, have read and understand this document and agree to adhere to the restrictions and warnings stated therein.

Name of Institution:

_____

Principal Investigator (typed or printed):

_____

Signature:

_____

Institutional Official who can make legal commitments on behalf of the Institution (typed or printed):

_____

Title:

_____

Signature of Institutional Official:

_____

Date:

_____

CFR Form 12/29/01